K102536
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510(k) SUMMARY

Subject Device:	**VITALA™ Continence Control Device**
Date Prepared:	November 29, 2010
Applicant:	ConvaTec Inc. 200 Headquarters Park Drive Skillman, New Jersey 08558
Contact:	Charles Ryan Associate Director, US Regulatory Affairs Tel: 908-904-2541 Fax: 908-904-2235
Device Trade Name:	Vitala™ Continence Control Device
Classification Name:	Ostomy Pouch and Accessory (ref. 21 CFR 876.5900; Product Code EZQ)
Device Class:	Class I

Predicate Device Trade Name:	Vitala™ Continence Control Device
Classification Name:	Ostomy Pouch and Accessory (ref. 21 CFR 876.5900; Product Code EZQ)
Device Class:	Class I
510(k) Substantial Equivalence:	K083785 – determined substantially equivalent on April 2, 2010

DEVICE DESCRIPTION

The Vitala™ Continence Control Device is a pouchless ostomy device consisting of a self-inflating Air Seal which contacts a stoma and is held against the stoma with a low pressure, allowing flatus to be deodorized and vented while retaining stool. The Air Seal contains a soft foam insert that expands to fill the Air Seal, causing the Air Seal to expand with it. As it expands, the Air Seal gently contacts the stoma and conforms to the

shape of the stoma, and is held against the stoma with a low pressure. The Air Seal will re-inflate to remain in contact with the stoma if the stoma retracts or moves away from the Air Seal.

The Vitala™ Continence Control Device also includes an expandable container to collect stool during removal of the device. This single use device is designed to be used only with a 1 ¾" (45mm) or 2 ¼" (57mm) ConvaTec Natura® skin barrier, and will accommodate a range of stoma diameters.

The Vitala™ Continence Control Device is indicated for individuals with end colostomies. The device is not intended for use until the abdomen and peristomal area have fully healed from bowel surgery (typically 6-12 weeks post surgery), or for use with a stoma protrusion greater than 2 cm (when lying down). The device should also not be used in individuals with end colostomies with a history of chronic liquid stool. ConvaTec Moldable Technology™ skin barriers should not be used with the Vitala™ device.

This 510(k) notification concerns modification of the labeling for the Vitala™ Continence Control Device to allow an expanded wear time of up to 12 hours per day for the device as well as expanded compatibility with ConvaTec Natura® convex products. Otherwise, the design, materials, and manufacture of the device remain unchanged from its description in 510(k) Premarket Notification K083785, except that its deflation shield is now made from polypropylene.

INDICATIONS FOR USE

The VITALA™ Continence Control Device is a single-use device intended to prevent the release of stool from an end colostomy while allowing any flatus from the stoma to be deodorized and released.

To be used only with a 1 ¾ in. (45 mm) or 2 ¼ in. (57 mm) ConvaTec NATURA® skin barrier. Not intended for use with ConvaTec Moldable Technology™ skin barriers.

CLINICAL SUMMARY

ConvaTec has performed two clinical studies to assess the safety and effectiveness of the Vitala™ Continence Control Device with an extended wear time of up to 12 hours per day as well as its compatibility with ConvaTec Natura® convex products.

Clinical Study #1

A non-randomized, open-label, multi-center, multi-national (conducted in the USA and Europe) clinical study was initiated on April 17, 2009 and completed on January 16, 2010.

The planned methodology was to enroll 75 subjects with an end colostomy of at least 12 weeks duration with formed or semi-formed effluent, who had the ability to wear a size 45mm or 57mm ConvaTec Natura® skin barrier flange, and a

stoma that protruded no more than 2cm at rest (supine/on the back), as well as the ability to do complete self-care.

The primary objective of this clinical study was to assess safety during 12 hours of Vitala™ device wear by measuring the frequency of adverse events (AEs) related to stoma (including gastro-intestinal (GI), stomal and surrounding skin events), microbiology profile and stomal vascularity.

Seventy-eight subjects were enrolled in this study across study centers in the USA and Europe. Thirty-three subjects (42.3%) either withdrew or were discontinued from the study while 45 subjects (57.7%) completed the study per protocol. A total of 66 subjects wore the Vitala™ device.

Subjects in general rated the Vitala™ device as good or very good in its ability to restore continence (86.9%).

Overall, the rate of AEs during the Usual Stage (where subjects used their usual pouch system) and the Vitala™ Stage was identified at 0.01 per patient per day. Nausea/vomiting/diarrhea were the most commonly reported AEs (16 subjects) followed by abdominal pain (7 subjects) and constipation (5 subjects). Most AEs were mild or moderate in nature; however, there were 27 severe or very severe AEs, of which two were possibly related to the Vitala™ device.

Microbiology results showed that baseline evaluations established the presence of normal microflora and common microbial intestinal toxins. No obvious or harmful changes to the normal flora were noted when samples obtained during the Vitala™ Stage were compared to baseline samples. No aberrant flora were noted in the samples collected for GI events.

Stoma vascularity results showed that there was no significant difference in mean oxygen saturation (SO_2) values. There was also no evidence of the systematic development of hypoxic regions in subjects who completed the study.

Overall, results from this study indicate that the Vitala™ device is safe and effective at restoring continence when worn up to 12 hours daily.

Clinical Study #2

A non-randomized, open-label, multi-center clinical study was conducted in the USA. The study was initiated on February 3, 2010 and completed on April 6, 2010, with primary objective to assess the safety of the Vitala™ Continence Control Device with 45mm and 57mm sizes of ConvaTec Natura® convex products during 12 hours of daily wear. Approximately 15 subjects who had been using some form of convex products and 10 subjects who did not normally use convexity were to be enrolled in this study.

The planned methodology was to enroll subjects with an end colostomy of at least 12 weeks duration with formed or semi-formed effluent, current users of convex skin barriers or convex inserts (enrollment targeted 15 convex users and 10 non-convex users), willingness to wear a ConvaTec Natura® convex product in 45mm or 57mm size with a stoma opening size from 13mm up to 50mm, a stoma that protruded no more than 2cm at rest (supine / lying down on the back) and an ability to do complete self-care.

Twenty-seven subjects were enrolled in this study in the USA. Fifteen subjects who were convex users at baseline and 12 subjects who were non-convex users at baseline were enrolled into the study. Twenty-three subjects (85.2%) completed the study while four subjects (14.8%) discontinued from the study.

Subjects in general rated the Vitala™ device as "good" or "very good" in its ability to restore continence (64%).

Overall, the rate of adverse events (AEs) during the Convex Stage (where subjects used ConvaTec Natura® convex products prior to use of the Vitala™ device) was 0.03 and during the Vitala™ Stage it was identified at 0.02 per patient per day. Nausea/vomiting/diarrhea were the most commonly reported AEs (4 subjects) followed by bleed/bruise (trauma) to stoma wound, constipation and loose stool (3 subjects each). Most AEs were mild or moderate in nature and there was only one very severe AE, which was not considered to be related to the study treatment.

Stoma vascularity results provided no evidence of any changes in stoma and peristomal skin oxygen saturation (SO_2) or the development of hypoxic regions in the stoma and hyperoxic regions in peristomal skin as a result of wearing the Vitala™ device with convex products.

Safety results showed no Vitala™ device related serious adverse events (SAEs) and no abnormal findings during the Vitala™ Stage. Stoma vascularity results provided no evidence of any changes in stoma and peristomal skin SO_2 or the development of hypoxic regions in the stoma and hyperoxic regions in peristomal skin as a result of wearing the Vitala™ device with convex products.

Overall, results from this study indicate that the Vitala™ device is safe and effective at restoring continence when worn up to 12 hours with convex products.

OVERALL CONCLUSION

There are no significant differences in the intended use between the subject and predicate Vitala™ Continence Control Devices. The Vitala™ device is non-invasive to the stoma, and has demonstrated substantial equivalence as well as safety and effectiveness through use in clinical studies, microbiology studies, and vascularity testing of the stoma. The design, materials, and manufacture of the device remain unchanged from how it was

described in 510(k) Premarket Notification K083785, except that its Deflation Shield is now made from polypropylene.

Based on the evidence provided, we propose that Vitala™ Continence Control Device can be used safely and effectively for individuals with end colostomies to prevent the release of stool from an end colostomy, for a wear time of up to twelve hours per day as well as with ConvaTec Natura® convex products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Charles Ryan
Associate Director, U.S. Regulatory Affairs
ConvaTec, Inc.
200 Headquarters Park Drive
SKILLMAN NJ 08558

DEC 1 2010

Re: K102536
Trade/Device Name: VITALA Continence Control Device
Regulation Number: 21 CFR §876.5900
Regulation Name: Ostomy pouch and accessories
Regulatory Class: I
Product Code: EZQ
Dated: September 1, 2010
Received: September 3, 2010

Dear Mr. Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): *Not Yet Assigned* K102536

DEC 1 2010

Device Name: VITALA™ Continence Control Device

Indications For Use:

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Prescription Use ___ (21 CFR 801 Subpart D) AND/OR Over the Counter Use XX (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102536